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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,418	03/01/2002	David A. Edwards	2846.1001-028	8180

7590

07/29/2003

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,418

Applicant(s)

EDWARDS ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 12-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s): Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's election of Group I, claims 1-11 and insulin as the hormone in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 3 is withdrawn from consideration as being drawn to a non-elected specie. Claims 1-2, and 4-11 are herein examined on the merits in so far as they read on the elected specie of insulin.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17 of U.S. Patent No. 5,874,064.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass the instant claims since they are directed to any therapeutic agent. Moreover insulin is enumerated in the specification of the patent as one of the therapeutic agents, see col. 10, lines 36-47 in particular.

Claims 1,2,4,7-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17, 20, and 27 of U.S. Patent No. 5,855,913. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the patented claims overlaps with the instant claims. The instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 6-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter is between 1-3 microns the claims overlap.

Claims 1,2, and 4-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20, 23 and 26 of U.S. Patent No. 6,436,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims overlap with the instant claims in so far as a MMD of between 6 and 30 microns is claimed and an aerodynamic diameter of between 1-4.6999 microns is claimed

Claims 1,2,4,5,7-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 22 of U.S. Patent No. 5,985,309.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 5.1-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter is between 1-46999 microns the claims overlap.

Claims 1,2,4 and 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 20-21 of U.S. Patent No. 6,503,480 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 6-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter is concerned in so far as the particles are between 1 micron and 4.6999 microns the claims overlap, see also example 7 and column 16.

Claims 1-2, 4-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-16 and 26-27 of U.S. Patent No. 6,254,854. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 6-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter

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is concerned in so far as the particles are between 1 micron and 4.6999 microns the claims overlap, see also example 7 and column 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,2, 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (USPN 6,423,344 B1).

Platz et al. (USPN 6,423,344 B1) teaches a method of delivering therapeutic agents such as insulin along with pharmaceutical carriers and excipients to the lung of a patient particles having a mass mean diameter of less than 10 microns and particles having a diameter of 0.4-5 microns, see claims 1,4-6, 13 and col. 6, line 38 to col. 8 line 21, col. 9, lines 11-67 and Tables 2-3, for example.

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Platz does not does not particularly teach the release profile of the insulin composition employed in its method, neither does it teach mass mean diameter greater than 20 microns.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the mass mean diameter of the particles. It would have also been obvious to recite the instant release profiles in the claims.

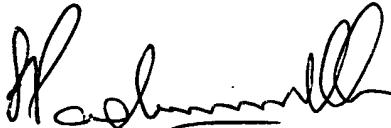
One of ordinary skill in the art would have been motivated to increase the mass mean diameter of the particles because employment of larger particles in a pulmonary inhalation method is known in the art. Note that the same composition, administered in the same manner would be reasonably expected to exhibit the same release profile.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
July 15, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

7/28/03